

DOCKET NO: 283829US0PCT

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF

THOMAS RUECKLE, ET AL.

EXAMINER: HAVLIN

SERIAL NO: 10/565,976

:

FILED: APRIL 28, 2006

ART UNIT: 1626

FOR: 2-IMINO-4-(THIO) OXO-5-POLY  
CYCLOVINYLAZOLINES FOR USE  
AS P13 KINASE INHIBITORS

**APPEAL BRIEF**

COMMISSIONER FOR PATENTS  
ALEXANDRIA, VIRGINIA 22313

SIR:

In accordance with 35 U.S.C. § 134, that the claims of the present application have been twice rejected, this brief is submitted in response to the final rejection dated April 28, 2009.

**REAL PARTY OF INTEREST**

The real parties of interest herein are Laboratories Serono, S.A., Switzerland.

**RELATED APPEALS AND INTERFERENCES**

To the best of Appellants' knowledge, there are no other appeals or interferences which will directly affect or be directly affected by, or have a bearing on, the Board's decision in this appeal.

**STATUS OF CLAIMS**

Claims 1-22 are active.

Claims 3, 6, 9, 10, 12-20, and 22 are withdrawn.

Claims 1, 2, 4, 7, 8, 11 and 21 are rejected.

Claims 1, 2, 4, 5, 7, 8, 11 and 21 are objected to for including non-elected subject matter.

Claims 1, 2, 4, 7, 8, 11 and 21 are appealed.

The appealed claims are presented in Appendix I.

**STATUS OF AMENDMENTS**

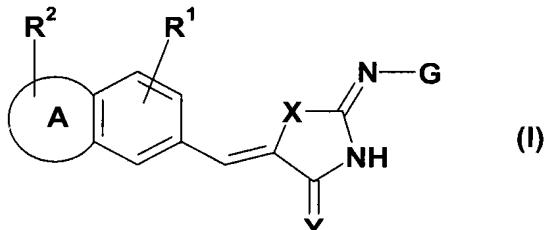
No outstanding amendments are present in this case.

**SUMMARY OF CLAIMED SUBJECT MATTER**

The invention claimed in the pending, rejected and appealed independent claim 1 with reference to exemplary support in the originally filed application is

An imino-azolinone-vinyl fused-benzene compound or its salt according to Formula

(I),



[page 7]

wherein A is an 5-8 membered heterocyclic group or an carbocyclic group which may be fused with an aryl, an heteroaryl, an cycloalkyl or an heterocycloalkyl; [page 19, line 3 to page 20, line 3]

X is S, O or  $-NR^3$ ; [page 20, line 8]

Y is S or O; [page 20, line 11]

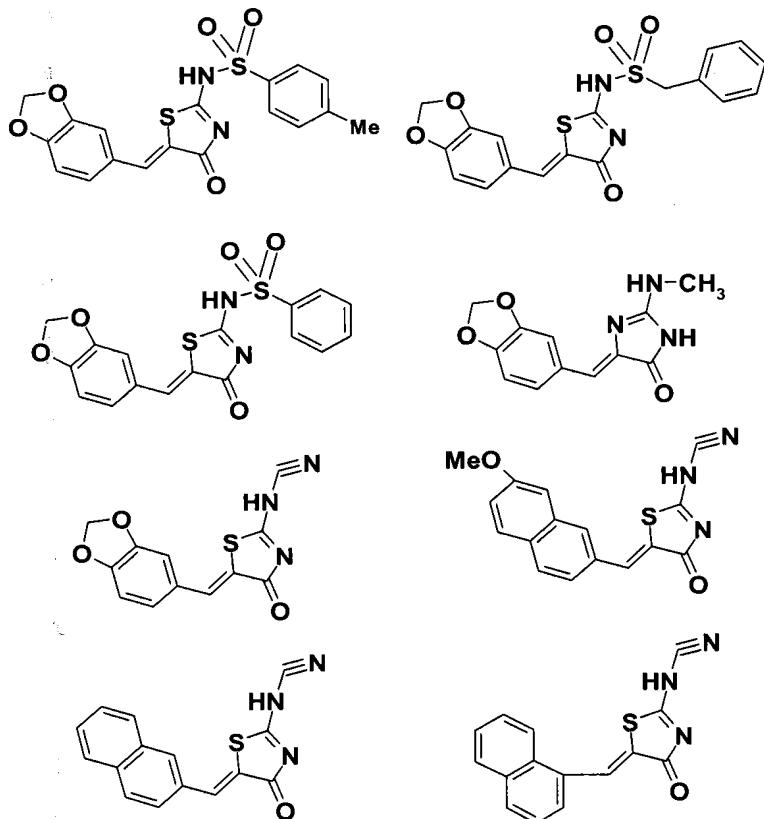
$R^1$  is selected from the group consisting of H, CN, carboxy, acyl,  $C_1-C_6$ -alkoxy, halogen, hydroxy, acyloxy,  $C_1-C_6$ -alkyl carboxy,  $C_1-C_6$ -alkyl acyloxy,  $C_1-C_6$ -alkyl alkoxy, alkoxycarbonyl,  $C_1-C_6$ -alkyl alkoxycarbonyl, aminocarbonyl,  $C_1-C_6$ -alkyl aminocarbonyl, acylamino,  $C_1-C_6$ -alkyl acylamino, ureido,  $C_1-C_6$ -alkyl ureido, amino,  $C_1-C_6$ -alkyl amino, ammonium, sulfonyloxy,  $C_1-C_6$ -alkyl sulfonyloxy, sulfonyl,  $C_1-C_6$ -alkyl sulfonyl, sulfinyl,  $C_1-C_6$ -alkyl sulfinyl, sulfanyl,  $C_1-C_6$ -alkyl sulfanyl, sulfonlamino,  $C_1-C_6$ -alkyl sulfonlamino and carbamate; [page 20, lines 13-24]

$R^2$  is selected from the group consisting of H, halogen, acyl, amino,  $C_1-C_6$ -alkyl,  $C_2-C_6$ -alkenyl,  $C_2-C_6$ -alkynyl,  $C_1-C_6$ -alkyl carboxy,  $C_1-C_6$ -alkyl acyl,  $C_1-C_6$ -alkyl alkoxycarbonyl,  $C_1-C_6$ -alkyl aminocarbonyl,  $C_1-C_6$ -alkyl acyloxy,  $C_1-C_6$ -alkyl acylamino,  $C_1-C_6$ -alkyl ureido,  $C_1-C_6$ -alkyl carbamate,  $C_1-C_6$ -alkyl amino,  $C_1-C_6$ -alkyl alkoxy,  $C_1-C_6$ -

alkyl sulfanyl, C<sub>1</sub>-C<sub>6</sub>-alkyl sulfinyl, C<sub>1</sub>-C<sub>6</sub>-alkyl sulfonyl, C<sub>1</sub>-C<sub>6</sub>-alkyl sulfonylaminoaryl, aryl, heteroaryl, C<sub>3</sub>-C<sub>8</sub>-cycloalkyl or heterocycloalkyl, C<sub>1</sub>-C<sub>6</sub>-alkyl aryl, C<sub>1</sub>-C<sub>6</sub>-alkyl heteroaryl, C<sub>2</sub>-C<sub>6</sub>-alkenyl-aryl or -heteroaryl, C<sub>2</sub>-C<sub>6</sub>-alkynyl aryl or -heteroaryl, carboxy, cyano, hydroxy, C<sub>1</sub>-C<sub>6</sub>-alkoxy, nitro, acylamino, ureido, sulfonylamino, sulfanyl, and sulfonyl; *[page 20, line 25 to page 21, line 13]*

G is a C<sub>1</sub>-C<sub>6</sub>-alkoxy, C<sub>1</sub>-C<sub>6</sub>-alkyl, C<sub>2</sub>-C<sub>6</sub>-alkenyl, C<sub>2</sub>-C<sub>6</sub>-alkynyl, C<sub>1</sub>-C<sub>6</sub>-alkyl aryl, or a sulfonyl moiety; *[page 21, lines 14-19]*

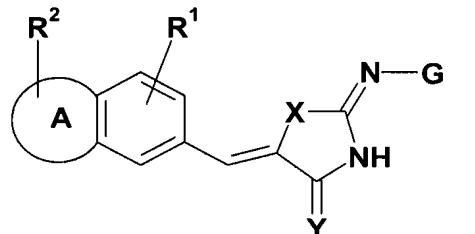
R<sup>3</sup> is selected from the group consisting of H and C<sub>1</sub>-C<sub>6</sub>-alkyl *[page 20, lines 8-9]*; with the proviso that the following 8 compounds are excluded :



*[page 17]*

The invention claimed in the pending, rejected and appealed independent claim 11 with reference to exemplary support in the originally filed application is

A composition comprising a carrier, adjuvant, diluent, excipient, or a combination thereof [*page 34, lines 22-27*] and an imino-azolinone-vinyl fused-benzene compound or its salt according to Formula (I)



[*page 7*]

wherein A is an 5-8 membered heterocyclic group or an carbocyclic group which may be fused with an aryl, an heteroaryl, an cycloalkyl or an heterocycloalkyl; [*page 19, line 3 to page 20, line 3*]

X is S, O or  $-NR^3$ ; [*page 20, line 8*]

Y is S or O; [*page 20, line 11*]

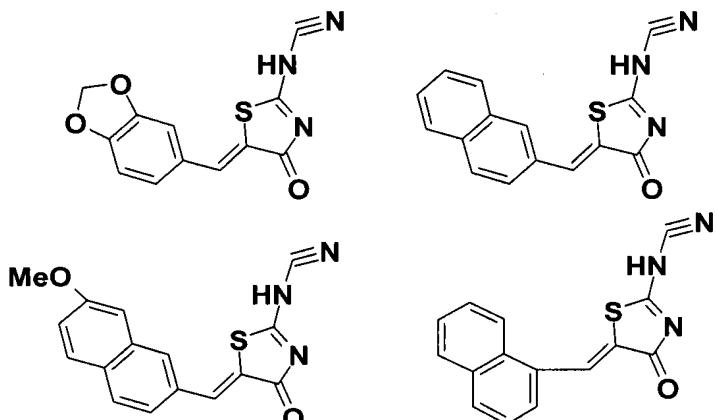
$R^1$  is selected from the group consisting of H, CN, carboxy, acyl,  $C_1-C_6$ -alkoxy, halogen, hydroxy, acyloxy,  $C_1-C_6$ -alkyl carboxy,  $C_1-C_6$ -alkyl acyloxy,  $C_1-C_6$ -alkyl alkoxy, alkoxycarbonyl,  $C_1-C_6$ -alkyl alkoxycarbonyl, aminocarbonyl,  $C_1-C_6$ -alkyl aminocarbonyl, acylamino,  $C_1-C_6$ -alkyl acylamino, ureido,  $C_1-C_6$ -alkyl ureido, amino,  $C_1-C_6$ -alkyl amino, ammonium, sulfonyloxy,  $C_1-C_6$ -alkyl sulfonyloxy, sulfonyl,  $C_1-C_6$ -alkyl sulfonyl, sulfinyl,  $C_1-C_6$ -alkyl sulfinyl, sulfanyl,  $C_1-C_6$ -alkyl sulfanyl, sulfonylamino,  $C_1-C_6$ -alkyl sulfonylamino and carbamate; [*page 20, line 13-24*]

$R^2$  is selected from the group consisting of H, halogen, acyl, amino,  $C_1-C_6$ -alkyl,  $C_2-C_6$ -alkenyl,  $C_2-C_6$ -alkynyl,  $C_1-C_6$ -alkyl carboxy,  $C_1-C_6$ -alkyl acyl,  $C_1-C_6$ -alkyl alkoxycarbonyl,  $C_1-C_6$ -alkyl aminocarbonyl,  $C_1-C_6$ -alkyl acyloxy,  $C_1-C_6$ -alkyl acylamino,  $C_1-C_6$ -alkyl ureido,

C<sub>1</sub>-C<sub>6</sub>-alkyl carbamate, C<sub>1</sub>-C<sub>6</sub>-alkyl amino, C<sub>1</sub>-C<sub>6</sub>-alkyl alkoxy, C<sub>1</sub>-C<sub>6</sub>-alkyl sulfanyl, C<sub>1</sub>-C<sub>6</sub>-alkyl sulfinyl, C<sub>1</sub>-C<sub>6</sub>-alkyl sulfonyl, C<sub>1</sub>-C<sub>6</sub>-alkyl sulfonylaminoaryl, aryl, heteroaryl, C<sub>3</sub>-C<sub>8</sub>-cycloalkyl, C<sub>3</sub>-C<sub>8</sub>-heterocycloalkyl, C<sub>1</sub>-C<sub>6</sub>-alkyl aryl, C<sub>1</sub>-C<sub>6</sub>-alkyl heteroaryl, C<sub>2</sub>-C<sub>6</sub>-alkenyl-aryl, C<sub>2</sub>-C<sub>6</sub>-alkenyl-heteroaryl, C<sub>2</sub>-C<sub>6</sub>-alkynyl aryl, C<sub>2</sub>-C<sub>6</sub>-alkynyl -heteroaryl, carboxy, cyano, hydroxy, C<sub>1</sub>-C<sub>6</sub>-alkoxy, nitro, acylamino, ureido, sulfonylamino, sulfanyl, and sulfonyl; **page 20, line 25 to page 21, line 13]**

G is a C<sub>1</sub>-C<sub>6</sub>-alkoxy, C<sub>1</sub>-C<sub>6</sub>-alky, C<sub>2</sub>-C<sub>6</sub>-alkenyl, C<sub>2</sub>-C<sub>6</sub>-alkynyl, C<sub>1</sub>-C<sub>6</sub>-alkyl aryl, or a sulfonyl moiety; **[page 21, lines 14-19]**

R<sup>3</sup> is selected from the group consisting of H and C<sub>1</sub>-C<sub>6</sub>-alkyl; with the proviso that the following 4 compounds are excluded:



. [Page 17]

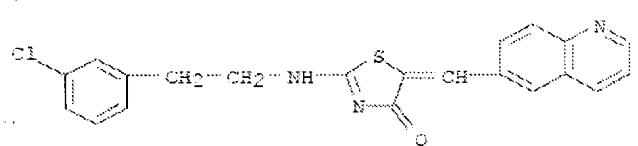
**GROUNDΣ OF REJECTION TO BE REVIEWED ON APPEAL**

The sole rejection to be reviewed on appeal is whether Claims 1, 2, 4, 7, 8, 11 and 21 are properly rejected under 35 USC 102(e) in view of PG PUB 2006/0293338 to Hasegawa *et al.*

**ARGUMENT**

The rejection outlined in the final Official Action of April 28, 2009 (OA) at page 3 sets forth the rejection

The prior art teaches the following compound which anticipate the claims:



This compound is found in Example 107 ([00372]) in the Hasegawa *et al* publication.

Then, the Examiner cites the specification at page 14, applying the broadest reasonable interpretation standard (OA at page 3-4). The final rejection provides no further basis to conclude why the Hasegawa compound falls within the scope of the claims.

It is by now well settled that the burden of establishing a *prima facie* case of anticipation resides with the Patent and Trademark Office. *In re Piasecki*, 745 F.2d 1468, 1472, 223 USPQ 785, 788 (Fed. Cir. 1984), quoting *In re Warner*, 379 F.2d 1011, 1016, 154 USPQ 173, 177 (CCPA 1967). Absent evidence which supports a rejection of the subject matter Applicants claim as is the case with this rejection, the Examiner's conclusion that the claims are unpatentable under 35 U.S.C. §102(e) must be withdrawn.

U.S. application serial no. 10/565,976  
Appeal Brief

1. The cited Hasegawa et al publication is not available as prior art for which it was cited

The present 371 application was filed on April 28, 2006 of a PCT application filed on July 27, 2004 and claims the benefit of European (EP) application 03102313.8 filed July 27, 2003, which fully supports the claimed invention.

The Hasegawa *et al* publication is available as prior art against this application based on the U.S. provisional application serial no. 60/428,384 to which it claims priority (35 U.S.C. § 102(e)). The provisional application of the Hasegawa *et al* publication was filed on November 22, 2002, which is prior to the earliest date to which the present application claims priority (EP application filed July 28, 2003). However, for the rejection to be sustained, the provisional application must support the subject matter upon which the Examiner relied in the rejection.

Example 107 (at page 35), i.e., the compound identified in the rejection was NOT present in that provisional. A copy of the Hasegawa *et al* provisional application is attached to this brief.

Therefore, the earliest effective prior art date of the Hasegawa *et al* publication for the subject matter relied upon in the rejection is the date the PCT was filed (November 18, 2003). While this date is before the filing date of the PCT application from which the present 371 application was filed, it is after the date of the European Patent application, July 27, 2003.

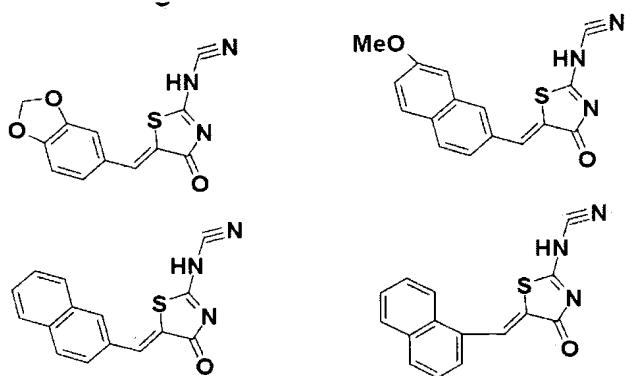
As Applicants European priority application provides support for the claims in the present U.S. application, the Hasegawa *et al* publication is not applicable prior art under 35 USC 102(e). In the Advisory Action of September 3, 2009, the Examiner stated at page 2:

Applicant also argues the priority date of the instant claims are earlier than the cited prior art. Upon review of the priority documents, limitations are presently in the claims that were not in the certified priority documents, therefore the priority date for the claims is the filing date of this application. Specifically, the limitations are the four additional proviso-ed compounds.

The Examiner's finding that the full scope of the subject matter defined in the pending claims, including the exclusionary proviso, is not described in EP 03102313.8 in the manner required under 35 U.S.C. § 112, 1<sup>st</sup> paragraph, is clearly erroneous. EP 03102313.8 shows that the Applicants were in possession of the full scope of the invention positively defined by the current claims as of its filing date.

Each of the limitations of Claim 1 and the supporting disclosure in EP 03102313.8:

1. The structure of formula (I) is disclosed on page 7, lines 7-9.
2. The definition of A is disclosed on page 17, liens 11-12.
3. The definition of X is disclosed on page 18 line 17.
4. The definition of Y is disclosed on page 18, line 19.
5. The definition of R<sup>1</sup> is disclosed on page 18, line 20 to page 19, line 4.
6. The definition of R<sup>2</sup> is disclosed on page 19, lines 6-22.
7. The definition of G is disclosed on page 19, line 24 to page 20, line 2.
8. The definition of R<sup>3</sup> is disclosed on page 18, lines 17-18.
9. The first four structures of the 8 compounds excluded from the claims are disclosed on page 20, starting at line 5.
10. The last four structures of the 8 compounds excluded from the claims are:



- a. Support is found in the disclosure for each of the substituent groups for formula (I) at least at:

- i. X at page 18, line 17
- ii. Y at page 18, line 19
- iii. R<sup>1</sup> at page 18, line 20 to page 19, line 5
- iv. R<sup>2</sup> at page 19, lines 7-22
- v. A at page 17, line 11 to page 18, line 16.

While the specific structures of the last four compounds excluded from Claim 1 are not depicted in structure form like the first four, they need not be. See *In re Parks*, 30 USPQ2d 1234 (BPAI 1994) and (*In re Johnson*, 558 F2d 1008 (Fed. Cir. 1977).

As is made clear in the present application, different types of substitutents and compounds are disclosed. The claims as defined make clear that the claims cover certain aspects of the disclosed compound falling within the general formula (I) at page 7 and do not cover other compounds. Such an exclusionary limitation is proper under MPEP 2173.05(i).

In *In re Parks*, the Board reversed the Examiner's new matter/written description rejection of claims containing the negative limitation "in the absence of a catalyst." In reversing the rejection, the Board stated (1) "clearly, the observation of a lack of literal support does not, in and of itself, establish a *prima facie* case for lack of adequate descriptive support" (*Id* at 1236). Here, the specification conveys that Applicants had possession of the compounds defined in the claims excluding some others. Applicants' possession of the concept is evident at least in the portions of the EP application detailed above.

Similarly, the Federal Circuit's decision in *In re Johnson* dictates withdrawal of the pending rejection as well. In *In re Johnson*, the issue was whether provisos excluding particular species which had been disclosed in the application constituted new matter/failed to satisfy the written description requirement. In holding that the provisos were proper, the Federal Circuit stated (at page 1019):

The notion that one who fully discloses, and teaches those skilled in the art how to make and use, a genus and numerous species therewithin, has somehow failed to

disclose, and teach those skilled in the art how to make and use, that genus minus two species, and has thus failed to satisfy the requirements of § 112, first paragraph, appears to result from a hypertechnical application of legalistic prose relating to that provision of the statute. All that happened is that appellants narrowed their claims to avoid having them read on a lost interference count.

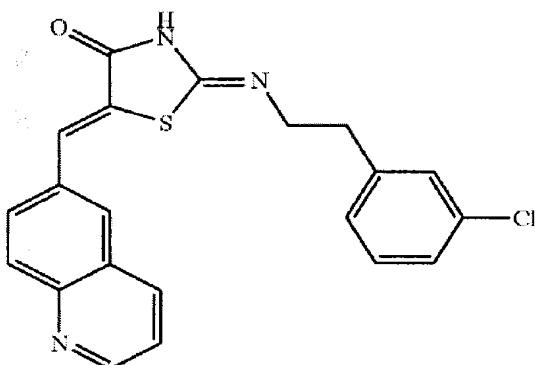
Similarly, here, all that is happening is that Applicants have presented claims to focus on fully disclosed embodiments to the exclusion of other embodiments. Thus, written descriptive support for the full-scope of the claims is positively found in the EP application.

Support for the present claims in the pending application is shown using Claim 1 as illustration in the Summary of Claimed Subject Matter detailed earlier in this brief. As the present application is a 371 of PCT/EP2004/051625, support for the subject matter in the claims is found at the same pages of the PCT application.

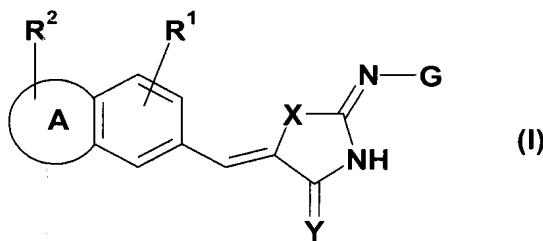
2. The reliance on Example 107 in the Hasegawa *et al* publication and the Hasegawa provisional application in the Advisory Action is erroneous

In the final Office Action, the Examiner cited to a CAS database search corresponding to Example 107 ([00372]) in the publication. Example 107 does not fall within the scope of the defined subject matter in the claims.

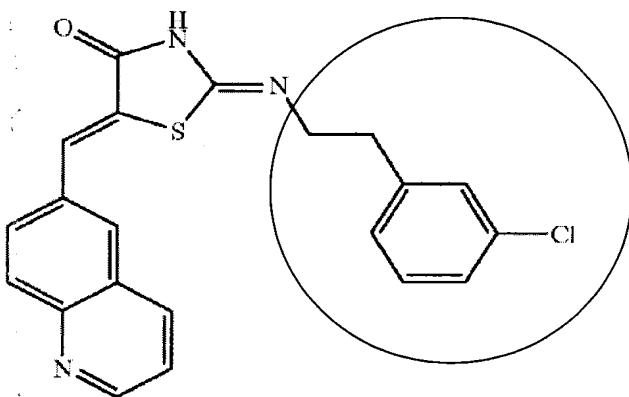
Example 107 is:



The compound of formula I set forth in Claim 1 (see Appendix I):



As set forth in Claim 1 of the present application, G is “a C<sub>1</sub>-C<sub>6</sub>-alkoxy, C<sub>1</sub>-C<sub>6</sub>-alkyl, C<sub>2</sub>-C<sub>6</sub>-alkenyl, C<sub>2</sub>-C<sub>6</sub>-alkynyl, C<sub>1</sub>-C<sub>6</sub>-alkyl aryl, or a sulfonyl moiety” (see Appendix I). Now looking at Example 107 with emphasis added to a portion of the molecule that corresponds to “G” in the claimed formula (I).



G in the compound of the claims cannot be the alkyl-phenyl substituted by chlorine that is required in example 107.

While Appellants understand that, during the prosecution of an application in the Office, claims are to be given their broadest reasonable interpretation consistent with the teaching in the specification (*In re Bond*, 710 F.2d 831, 833 (Fed. Cir. 1990)), it is error to disregard express limitations in the claims. The Examiner may not set up a “strawman” claim and reject it rather than subject matter encompassed by the actual claims.

Based on the reference (without discussion) of the present specification and the broadest reasonable interpretation of the claims alluded to in the final rejection, a reasonable inference that can be drawn from the Examiner’s rejection of the claims under 35 U.S.C. § 102(e) referencing Example 107 of Hasegawa is that the Examiner interprets the phrase “G is

Appeal Brief

C<sub>1</sub>-C<sub>6</sub>-alkoxy, C<sub>1</sub>-C<sub>6</sub>-alkyl, . . . C<sub>1</sub>-C<sub>6</sub> alkyl aryl or a sulfonyl moiety" in the claims in light of the Specification at p. 21 to mean "G is substituted or unsubstituted . . . C<sub>1</sub>-C<sub>6</sub> alkyl aryl . . . or a sulfonyl moiety" as a matter of law. Then, the Specification at p.14 defines "substituted or unsubstituted" to include halogen with page 12, line 21 to include chloro as a halogen. This presumption appears to have been confirmed by the Examiner in the Advisory Action of September 3, 2009 where it is stated at page 2:

Continuation of 11. does NOT place the application in condition for allowance because: Applicant argues that the examples cited by the examiner do not fall within the scope of the instant claims. As discussed in the final office action of 4/28/09, the specification allows for substitutions on groups such as the alternatives listed in "G" therefore, unless the claims recite unsubstituted forms of the alternatives, the broadest reasonable interpretation of the claims includes the prior cited examples.

The Examiner's claim interpretation is erroneous as a matter law. As defined in the specification at page 8, lines 1-2: "C<sub>1</sub>-C<sub>6</sub> alkyl aryl" refers to C<sub>1</sub>-C<sub>6</sub> alkyl groups having an aryl substituent, including benzyl, phenethyl and the like." A C<sub>1</sub>-C<sub>6</sub> alkyl aryl as is defined in the claims cannot be reasonably interpreted in light of the supporting Specification to mean a chloro substituted C<sub>1</sub>-C<sub>6</sub> alkyl aryl group. While there is no dispute as to what is stated in the specification, the plain language of Claim 1 states: G is . . . a C<sub>1</sub>-C<sub>6</sub> alkyl aryl (contrast to G comprises . . . a C<sub>1</sub>-C<sub>6</sub> alkyl aryl or G is . . . a substituted C<sub>1</sub>-C<sub>6</sub> alkyl aryl).

Thus, the conclusion underlying the rejection is based on clearly erroneous findings and the rejection cannot stand.

3. The reliance on Example 64 in the Hasegawa et al publication and the Hasegawa provisional application in the Advisory Action is erroneous

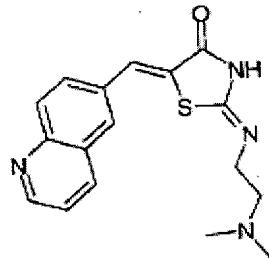
In the Advisory Action mailed August 14, 2009 at page 2, the Examiner newly cited

Example 64 stating:

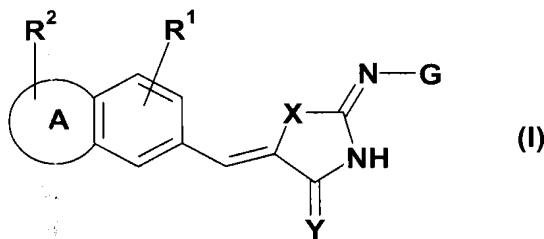
Continuation of 11. does NOT place the application in condition for allowance because: the prior art cited anticipates the claims and the CAPLUS document provides examples within the scope of the claims. See for example "Example 64" in the provisional application as well as the other numerous species therein which anticipate the claims. Therefore, the claims were properly rejected under 102(e).

Example 64 from page 45 of the provisional application (which is also found in the Hasegawa et al publication at page 26, paragraph [0280]) is:

**Example 64**  
**2-(2-Dimethylamino-ethylimino)-5-quinolin-6-ylmethylenethiazolidin-4-one**

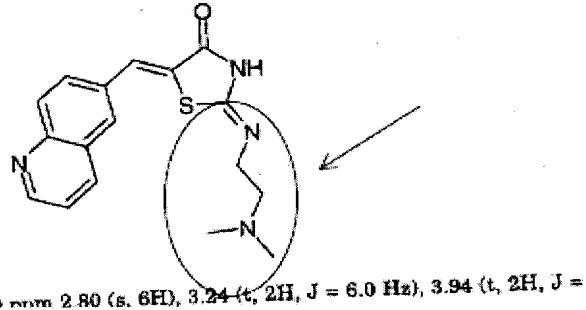


The compound of formula I set forth in Claim 1 (see Appendix I):



As set forth in Claim 1 of the present application, G is "a C<sub>1</sub>-C<sub>6</sub>-alkoxy, C<sub>1</sub>-C<sub>6</sub>-alkyl, C<sub>2</sub>-C<sub>6</sub>-alkenyl, C<sub>2</sub>-C<sub>6</sub>-alkynyl, C<sub>1</sub>-C<sub>6</sub>-alkyl aryl, or a sulfonyl moiety" (see Appendix I). Now looking at Example 64 with emphasis added to a portion of the molecule that corresponds to "G" in the claimed formula (I).

**Example 64**  
**2-(2-Dimethylamino-ethylimino)-5-quinolin-8-ylmethylenethiazolidin-4-one**



G in the compound of the claims is not a dimethyl amino substituted ethane group that is required in example 64.

Therefore, like the previous Example 107, Example 64 of the provisional application or the Hasegawa publication does not fall within the scope of the claims. The examples of the Hasegawa *et al* provisional application do not include any compound falling within the scope of the claims.

Based on the reference (without discussion) of the present specification and the broadest reasonable interpretation of the claims alluded to in the final rejection, a reasonable inference that can be drawn from the Examiner's rejection of the claims under 35 U.S.C. § 102(e) referencing Example 64 of Hasegawa is that the Examiner interprets the phrase "G is C<sub>1</sub>-C<sub>6</sub>-alkoxy, C<sub>1</sub>-C<sub>6</sub>-alkyl, . . . or a sulfonyl moiety" in the claims in light of the Specification at p. 21 to mean "G is substituted or unsubstituted C<sub>1</sub>-C<sub>6</sub>-alkoxy, C<sub>1</sub>-C<sub>6</sub>-alkyl, . . . or a sulfonyl moiety" as a matter of law. Then, the Specification at p.14 defines "substituted or unsubstituted" to include alkyl substituted by amino. This presumption appears to have been confirmed by the Examiner in the Advisory Action of September 3, 2009 where it is stated at page 2:

Continuation of 11, does NOT place the application in condition for allowance because: Applicant argues that the examples cited by the examiner do not fall within the scope of the instant claims. As discussed in the final office action of 4/28/09, the specification allows for substitutions on groups such as the alternatives listed in "G" therefore, unless the claims recite unsubstituted forms of the alternatives, the broadest reasonable interpretation of the claims includes the prior cited examples.

The Examiner's claim interpretation is erroneous as a matter law. While claims are to be given their broadest reasonable interpretation consistent with the teaching in the specification, an interpretation that is unreasonable and disregards express limitations in the claims cannot be sustained (*In re Bond, Id.*).

As defined in the specification at page 7, lines 17-18: "C<sub>1</sub>-C<sub>6</sub>-alkyl" refers to monovalent alkyl groups having 1 to 6 carbon atoms." A C<sub>1</sub>-C<sub>6</sub>-alkyl group as is defined in the claims cannot be reasonably interpreted in light of the supporting Specification to mean an amine substituted C<sub>1</sub>-C<sub>6</sub>-Alkyl group. While there is no dispute as to what is stated in the specification, the plain language of Claim 1 states: G is . . . a C<sub>1</sub>-C<sub>6</sub> alkyl (contrast to G comprises . . . a C<sub>1</sub>-C<sub>6</sub> alkyl or G is . . . a substituted a C<sub>1</sub>-C<sub>6</sub> alkyl).

Thus, as the conclusion underlying the rejection relying on Example 64 is also clearly erroneous, the rejection cannot be sustained.

CONCLUSION

It is respectfully submitted that the rejection is erroneous and indeed was raised improperly. Accordingly, it is requested that the rejection be reversed and remanded back to the Examining division of the Patent Office for further consideration on the merits, including consideration and search to non-elected species be conducted, and a Notice of Allowance indicating all pending claims are allowable.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,  
MAIER & NEUSTADT, P.C.

  
\_\_\_\_\_  
Daniel J. Pereira  
Registration No. 45,518

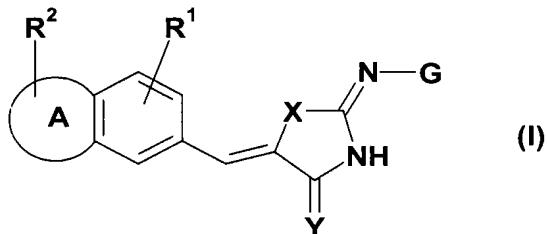
Customer Number  
**22850**

Tel: (703) 413-3000  
Fax: (703) 413 -2220  
(OSMMN 08/07)

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**APPENDIX 1 (CLAIMS)**

Claim 1 (Rejected) An imino-azolinone-vinyl fused-benzene compound or its salt according to Formula (I),



wherein A is an 5-8 membered heterocyclic group or an carbocyclic group which may be fused with an aryl, an heteroaryl, an cycloalkyl or an heterocycloalkyl;

X is S, O or  $-NR^3$ ;

Y is S or O;

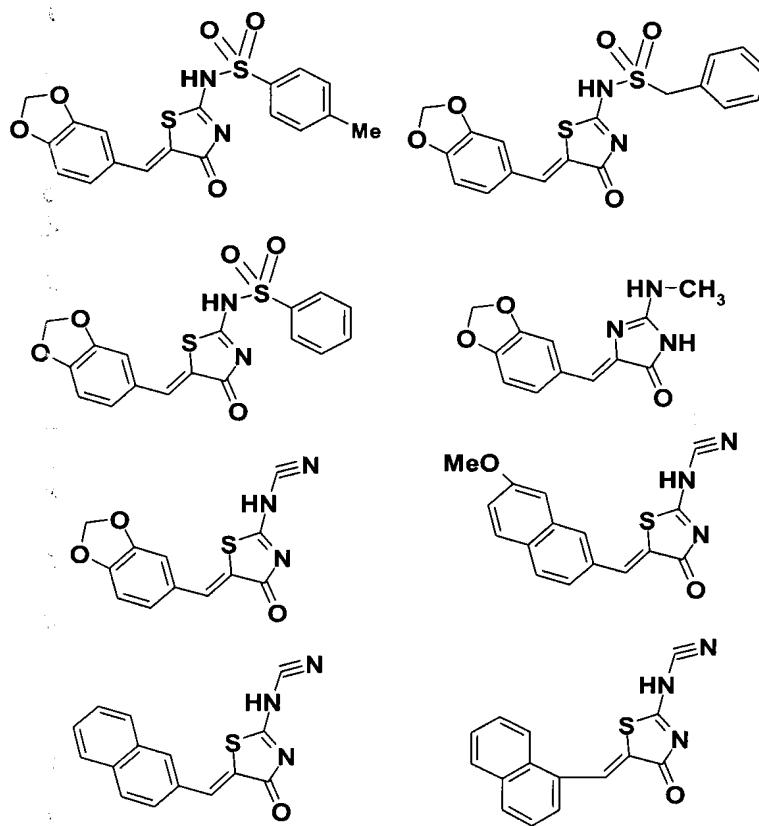
$R^1$  is selected from the group consisting of H, CN, carboxy, acyl,  $C_1-C_6$ -alkoxy, halogen, hydroxy, acyloxy,  $C_1-C_6$ -alkyl carboxy,  $C_1-C_6$ -alkyl acyloxy,  $C_1-C_6$ -alkyl alkoxy, alkoxy carbonyl,  $C_1-C_6$ -alkyl alkoxy carbonyl, aminocarbonyl,  $C_1-C_6$ -alkyl aminocarbonyl, acylamino,  $C_1-C_6$ -alkyl acylamino, ureido,  $C_1-C_6$ -alkyl ureido, amino,  $C_1-C_6$ -alkyl amino, ammonium, sulfonyloxy,  $C_1-C_6$ -alkyl sulfonyloxy, sulfonyl,  $C_1-C_6$ -alkyl sulfonyl, sulfinyl,  $C_1-C_6$ -alkyl sulfinyl, sulfanyl,  $C_1-C_6$ -alkyl sulfanyl, sulfonylamino,  $C_1-C_6$ -alkyl sulfonylamino and carbamate;

$R^2$  is selected from the group consisting of H, halogen, acyl, amino,  $C_1-C_6$ -alkyl,  $C_2-C_6$ -alkenyl,  $C_2-C_6$ -alkynyl,  $C_1-C_6$ -alkyl carboxy,  $C_1-C_6$ -alkyl acyl,  $C_1-C_6$ -alkyl alkoxy carbonyl,  $C_1-C_6$ -alkyl aminocarbonyl,  $C_1-C_6$ -alkyl acyloxy,  $C_1-C_6$ -alkyl acylamino,  $C_1-C_6$ -alkyl ureido,  $C_1-C_6$ -alkyl carbamate,  $C_1-C_6$ -alkyl amino,  $C_1-C_6$ -alkyl alkoxy,  $C_1-C_6$ -alkyl sulfanyl,  $C_1-C_6$ -alkyl sulfinyl,  $C_1-C_6$ -alkyl sulfonyl,  $C_1-C_6$ -alkyl sulfonylamino aryl, aryl, heteroaryl,  $C_3-C_8$ -cycloalkyl or heterocycloalkyl,  $C_1-C_6$ -alkyl aryl,  $C_1-C_6$ -alkyl heteroaryl,  $C_2-C_6$ -alkenyl-aryl or -heteroaryl,  $C_2-C_6$ -alkynyl aryl or -heteroaryl, carboxy,

cyano, hydroxy, C<sub>1</sub>-C<sub>6</sub>-alkoxy, nitro, acylamino, ureido, sulfonylamino, sulfanyl, and sulfonyl;

G is a C<sub>1</sub>-C<sub>6</sub>-alkoxy, C<sub>1</sub>-C<sub>6</sub>-alkyl, C<sub>2</sub>-C<sub>6</sub>-alkenyl, C<sub>2</sub>-C<sub>6</sub>-alkynyl, C<sub>1</sub>-C<sub>6</sub>-alkyl aryl, or a sulfonyl moiety;

R<sup>3</sup> is selected from the group consisting of H and C<sub>1</sub>-C<sub>6</sub>-alkyl; with the proviso that the following 8 compounds are excluded :



Claim 2 (Rejected).

Claim 3 (Withdrawn).

Claim 4 (Rejected): The imino-azolinone-vinyl fused-benzene compound or its salt according to claim 1, wherein R<sup>1</sup>, R<sup>2</sup>, or R<sup>1</sup> and R<sup>2</sup> are H.

Claim 5 (Objected): The imino-azolinone-vinyl fused-benzene compound or its salt according to claim 1, wherein G is a C<sub>1</sub>-C<sub>6</sub>-alkoxy, or a sulfonyl moiety.

Claim 6 (Withdrawn).

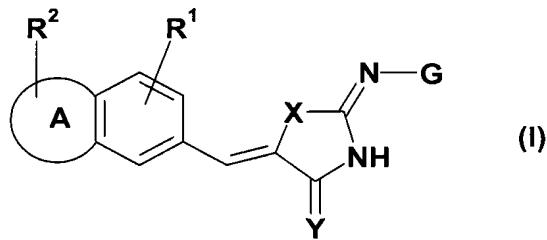
Claim 7 (Rejected): The imino-azolinone-vinyl fused-benzene compound or its salt according to claim 1, wherein G is a sulfonyl moiety of the formula -SO<sub>2</sub>-R<sup>4</sup>, wherein R<sup>4</sup> is selected from the group consisting of H, C<sub>1</sub>-C<sub>6</sub>-alkyl, C<sub>2</sub>-C<sub>6</sub>-alkenyl, C<sub>2</sub>-C<sub>6</sub>-alkynyl, C<sub>1</sub>-C<sub>6</sub>-alkyl carboxy, C<sub>1</sub>-C<sub>6</sub>-alkyl acyl, C<sub>1</sub>-C<sub>6</sub>-alkyl alkoxy carbonyl, C<sub>1</sub>-C<sub>6</sub>-alkyl aminocarbonyl, C<sub>1</sub>-C<sub>6</sub>-alkyl acyloxy, C<sub>1</sub>-C<sub>6</sub>-alkyl acylamino, C<sub>1</sub>-C<sub>6</sub>-alkyl ureido, C<sub>1</sub>-C<sub>6</sub>-alkyl carbamate, C<sub>1</sub>-C<sub>6</sub>-alkyl amino, C<sub>1</sub>-C<sub>6</sub>-alkyl alkoxy, C<sub>1</sub>-C<sub>6</sub>-alkyl sulfanyl, C<sub>1</sub>-C<sub>6</sub>-alkyl sulfinyl, C<sub>1</sub>-C<sub>6</sub>-alkyl sulfonyl, C<sub>1</sub>-C<sub>6</sub>-alkyl sulfonyl aminoaryl, aryl, heteroaryl, C<sub>3</sub>-C<sub>8</sub>-cycloalkyl or heterocycloalkyl, C<sub>1</sub>-C<sub>6</sub>-alkyl aryl, C<sub>1</sub>-C<sub>6</sub>-alkyl heteroaryl, C<sub>2</sub>-C<sub>6</sub>-alkenyl-aryl, C<sub>2</sub>-C<sub>6</sub>-alkenyl-heteroaryl, C<sub>2</sub>-C<sub>6</sub>-alkynyl-aryl, C<sub>2</sub>-C<sub>6</sub>-alkynyl-heteroaryl, carboxy, hydroxy, C<sub>1</sub>-C<sub>6</sub>-alkoxy, acylamino, and sulfonylamino.

Claim 8 (Rejected): The imino-azolinone-vinyl fused-benzene compound or its salt according to claim 7, wherein R<sup>4</sup> is aryl, heteroaryl or C<sub>1</sub>-C<sub>3</sub> alkyl.

Claim 9 (Withdrawn).

Claim 10 (Withdrawn).

Claim 11 (Rejected): A composition comprising a carrier, adjuvant, diluent, excipient, or a combination thereof and an imino-azolinone-vinyl fused-benzene compound or its salt according to Formula (I)



wherein A is an 5-8 membered heterocyclic group or an carbocyclic group which may be fused with an aryl, an heteroaryl, an cycloalkyl or an heterocycloalkyl;

X is S, O or  $-NR^3$ ;

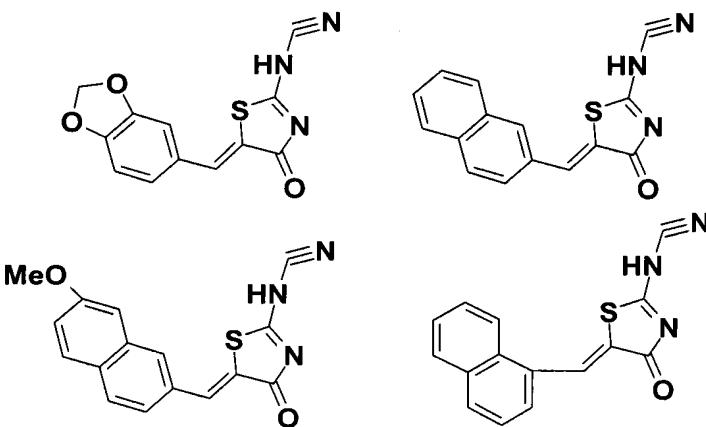
Y is S or O;

$R^1$  is selected from the group consisting of H, CN, carboxy, acyl,  $C_1-C_6$ -alkoxy, halogen, hydroxy, acyloxy,  $C_1-C_6$ -alkyl carboxy,  $C_1-C_6$ -alkyl acyloxy,  $C_1-C_6$ -alkyl alkoxy, alkoxycarbonyl,  $C_1-C_6$ -alkyl alkoxycarbonyl, aminocarbonyl,  $C_1-C_6$ -alkyl aminocarbonyl, acylamino,  $C_1-C_6$ -alkyl acylamino, ureido,  $C_1-C_6$ -alkyl ureido, amino,  $C_1-C_6$ -alkyl amino, ammonium, sulfonyloxy,  $C_1-C_6$ -alkyl sulfonyloxy, sulfonyl,  $C_1-C_6$ -alkyl sulfonyl, sulfinyl,  $C_1-C_6$ -alkyl sulfinyl, sulfanyl,  $C_1-C_6$ -alkyl sulfanyl, sulfonlamino,  $C_1-C_6$ -alkyl sulfonlamino and carbamate;

$R^2$  is selected from the group consisting of H, halogen, acyl, amino,  $C_1-C_6$ -alkyl,  $C_2-C_6$ -alkenyl,  $C_2-C_6$ -alkynyl,  $C_1-C_6$ -alkyl carboxy,  $C_1-C_6$ -alkyl acyl,  $C_1-C_6$ -alkyl alkoxycarbonyl,  $C_1-C_6$ -alkyl aminocarbonyl,  $C_1-C_6$ -alkyl acyloxy,  $C_1-C_6$ -alkyl acylamino,  $C_1-C_6$ -alkyl ureido,  $C_1-C_6$ -alkyl carbamate,  $C_1-C_6$ -alkyl amino,  $C_1-C_6$ -alkyl alkoxy,  $C_1-C_6$ -alkyl sulfanyl,  $C_1-C_6$ -alkyl sulfinyl,  $C_1-C_6$ -alkyl sulfonyl,  $C_1-C_6$ -alkyl sulfonlaminoaryl, aryl, heteroaryl,  $C_3-C_8$ -cycloalkyl,  $C_3-C_8$ -heterocycloalkyl,  $C_1-C_6$ -alkyl aryl,  $C_1-C_6$ -alkyl heteroaryl,  $C_2-C_6$ -alkenyl-aryl,  $C_2-C_6$ -alkenyl-heteroaryl,  $C_2-C_6$ -alkynyl aryl,  $C_2-C_6$ -alkynyl -heteroaryl, carboxy, cyano, hydroxy,  $C_1-C_6$ -alkoxy, nitro, acylamino, ureido, sulfonlamino, sulfanyl, and sulfonyl;

G is a C<sub>1</sub>-C<sub>6</sub>-alkoxy, C<sub>1</sub>-C<sub>6</sub>-alky, C<sub>2</sub>-C<sub>6</sub>-alkenyl, C<sub>2</sub>-C<sub>6</sub>-alkynyl, C<sub>1</sub>-C<sub>6</sub>-alkyl aryl, or a sulfonyl moiety;

R<sup>3</sup> is selected from the group consisting of H and C<sub>1</sub>-C<sub>6</sub>-alkyl; with the proviso that the following 4 compounds are excluded:



Claims 12-20 (Withdrawn).

Claim 21 (Rejected): A pharmaceutical composition comprising at least one thiazolidinone-vinyl fused-benzene derivative or its salt according to claim 1 and a pharmaceutically acceptable carrier, diluent, excipient, or combination thereof.

Claim 22 (Withdrawn).

**APPENDIX II (EVIDENCE)**

1. U.S. provisional application serial no. 60/428,384 to Hasegawa et al referenced in the Response filed on July 28, 2009.
2. European (EP) application 03102313.8 filed July 27, 2003, certified copy transmitted from the PCT office, receipt acknowledged at least in the Official Action of September 16, 2008 at page 1, item 12 a) 1.

**APPENDIX III (RELATED APPEALS AND INTERFERENCES)**

None.